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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,573	01/02/2002	Karen Anne Kelso	8830-14	9226
23973	7590	03/09/2004		
DRINKER BIDDLE & REATH ONE LOGAN SQUARE 18TH AND CHERRY STREETS PHILADELPHIA, PA 19103-6996			EXAMINER MICHENER, JENNIFER KOLB	
			ART UNIT 1762	PAPER NUMBER

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,573

Applicant(s)

KELSO, KAREN ANNE

Examiner

Jennifer K Michener

Art Unit

1762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/24/02; 6/18/02
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is no antecedent basis in claim 1 for the phrase "said naturally occurring dextran" in claim 3.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Malhotra et al. (5,212,008) in view of Bustard et al. (4,230,597).

Malhotra et al. teach a cross-linked dextran product, cross-linked by urea-formaldehyde (Beetle 65 product, for example) (abstract; col. 4, lines 50-55; col. 5, line 67; col. 6, lines 4-5; col. 8, lines 14-17). Examiner asserts that Malhotra inherently teaches cross-linking by formaldehyde and urea "condensation" and provides Bustard et al. to teach

the same. Bustard teaches that urea-formaldehyde is a well-known product which is prepared by the condensation reaction of formaldehyde with urea and that Beetle 65 is an example of such a product. Bustard is provided merely as a teaching of condensation inherency of the Malhotra reference.

While Malhotra does not teach that the crosslinked dextran of his invention is used as a bioresorbable sealant composition for coating a prosthetic graft, Examiner notes that such a limitation is merely the intended use of the product and that all product limitations are met by the Malhotra reference. Additionally, such limitations are merely present in the preamble of the claim.

The preamble is not a limitation on the claims if it merely states the purpose or intended use and the remainder of the claim completely defines the invention independent of the preamble. On the other hand, if claims cannot be read independently of the preamble and the preamble must be read to give meaning to the claim or is essential to point out the invention, it constitutes a claim limitation. *Stewart-Warner Corp v. City of Pontiac, Mich.* 219 USPQ 1162; *Marston v. J.C. Penney Co., Inc.* 148 USPQ 25; and *Kropa v. Robie and Mahlman*, 88 USPQ 478.

Regarding claim 2, the carboxymethyl dextran, amino dextran, and diethyl aminoethyl dextran taught by Malhotra are either naturally occurring or modified to contain reactive groups.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malhotra et al. in view of Bustard.

Malhotra teaches that which is disclosed above regarding the crosslinked dextran.

Malhotra further teaches that the polymeric dextran is crosslinked by exposure to the crosslinking agent, i.e., the urea-formaldehyde, in water (col. 5, lines 21-25; col. 6, lines 25-30 and 38). Malhotra teaches use of the crosslinking agent at 0.1-10 percent by weight, the urea portion thereof expected to lie within the range of 2-25% claimed by Applicant. As show in Malhotra's examples, the coating mixture is then heated at 100 °C, lying within the range claimed by Applicant. What Malhotra fails to teach is the separate addition of urea, then formaldehyde to the dextran solution. However,

Examiner notes that in general, the splitting of one step into two, where the processes are substantially identical or equivalent in terms of function, manner, and result, was held to not patentably distinguish the processes. *Ex parte Rubin*, 128 USPQ 440 (Bd. Pat App. 1959). Therefore it would have been obvious to one of ordinary skill in the art to split the step of exposing the dextran to urea-formaldehyde into two steps with the expectation of successful results.

Regarding the weight percentages of formaldehyde to urea, it is Examiner's position that it would have been obvious to one of ordinary skill in the art to optimize the varying amounts of the constituents of the crosslinking agent.

It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

8. Claims 3-4 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malhotra and Bustard, as discussed above, and further in view of Applicant's admitted state of the prior art.

Malhotra teaches a crosslinked dextran product, but fails to teach how dextran is originally made or its molecular weight.

Applicant disclosed on page 3 of the instant specification, that dextran is made by fermentation with the bacteria required by claim 3 to create a useful product with a molecular weight of 40,000.

Because Malhotra teaches the use of dextran for treatment with a crosslinking agent and Applicant discloses that it is known that dextran is first produced by fermentation as discussed above, Applicant's admitted state of the prior art would have reasonably suggested that the dextran of Malhotra was made by such a fermentation process. It would have been obvious to one of ordinary skill in the art to use the teachings of Applicant's admitted state of the prior art as a teaching of the source of Malhotra's dextran.

9. Claims 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bass et al. (5,292,362) in view of Lentz et al. (5,851,229) and Malhotra et al.

Bass et al. teaches the use of a crosslinked saccharide, such as dextran (col. 5, lines 9-17), as a watertight sealant for prosthetic material (col. 4, lines 15-18; col. 7, line 45) to coat implantable devices to enhance their strength and resistance to fluids, to seal pores in the weave of the material, and reduce thrombogenicity (col. 8, lines 6-11). What Bass fails to specifically teach is a method of coating such medical devices with dextran or a means to crosslink the dextran.

Lentz is cited to teach a method of coating flexible vascular grafts (col 1, lines 5-7) with crosslinked polysaccharide sealants useful in forming a resorbable, substantially blood-tight barrier on the graft (paragraph bridging columns 3 and 4; col. 4, line 62). Lentz coats such grafts by impregnating with the polysaccharide and subsequently cross-linking the polysaccharide and heat-drying at 60 °C (examples; abstract).

Since Bass teaches coating medical devices with a dextran polysaccharide to yield a water-tight seal and Lentz teaches a method of impregnating grafts with polysaccharide and then cross-linking to yield a water-tight seal, Lentz would have reasonably suggested the use of his coating method in the method of Bass to provide a means to coat specific medical devices with sealants.

What Bass in view of Lentz specifically fail to teach is the crosslinker.

Malhotra, as outlined above, teaches the use of urea-formaldehyde to crosslink dextran by including the urea-formaldehyde in the coating mixture and then heating.

Since Bass and Lentz together teach crosslinking/heat-drying dextran after coating grafts with the dextran, and Malhotra teaches crosslinking dextran by incorporating urea-formaldehyde into the dextran coating mixture, Malhotra would have reasonably suggested adding the crosslinker to the coating mixture of Bass in view of Lentz. It would have been obvious to one of ordinary skill in the art to use the teachings of Malhotra in the method of Bass and Lentz to provide Bass and Lentz with an effective way to obtain the crosslinked dextran coating desired by Bass and Lentz to provide water-tight seals to implantable medical device grafts.

Lentz teaches that the graft material may be e PTFE (col. 4, line 13).

Lentz teaches that the crosslinked polysaccharide may be plasticized with glycerol (P bridging columns 7 and 8).

Lentz inherently teaches grafts coated by the above method.

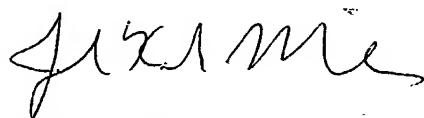
Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Machy et al. (US 2003/0163186 A1) teaches vascular grafts impregnated with crosslinked dextran, crosslinked by urea, etc. Groff teaches crosslinking temperatures for Beetle 65 urea-formaldehyde.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 571-272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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March 4, 2004